

## RECEIVED

AUG 1 4 2002

**TECH CENTER 1600/2900** 

PTO/SB/21 (6-98)
Approved for use through 09/30/2000. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Please type a plus sign (+) inside this box -> + Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

09/954,571 **Application Number** TRANSMITTAL September 11, 2001 Filing Date **FORM** Kenneth R. CHIEN First Named Inventor Group Art Unit (to be used for all correspondence after initial filing) 1646 UNKNOWN **Examiner Name** 6627-PA0123 Total Number of Pages in This Submission Attorney Docket Number **ENCLOSURES** (check all that apply) After Allowance Communication Assignment Papers Fee Transmittal Form (for an Application) to Group Appeal Communication to Board Fee Attached Drawing(s) of Appeals and Interferences Appeal Communication to Group Amendment / Response Licensing-related Papers (Appeal Notice, Brief, Reply Brief) Petition Routing Slip (PTO/SB/69) and Accompanying Petition After Final Proprietary Information Petition to Convert to a Affidavits/declaration(s) Status Letter Provisional Application Power of Attorney, Revocation Change of Correspondence Additional Enclosure(s) Extension of Time Request (please identify below): Form SB/08A; cited references; Terminal Disclaimer Express Abandonment Request return postcard Small Entity Statement Information Disclosure Statement Request for Refund Certified Copy of Priority Document(s) Remarks Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Colleen J. McKiernan Reg. No. 48,570 Individual name Signature Date August 6, 2002 CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the U. S. Postal Service as first class mail in an envelope addressed to: U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202 on this date: Typed or printed name Karen Johnson

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be send to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Shoron

Signature

Date

August 6, 2002



## **PATENT**

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER 37 C.F.R. §§ 1.97 and 1.98

INFORMATIO	ON DISCLE	SURE STATEMENT	TECH CENTER 1600/2900
Filed: September 11, 2001	)	Group Art Unit: 1646	AUG 1 4 2002
Serial No.: 09/954,571	)		RECEIVED
Kenneth R. CHIEN et al.	)	GENE TRANSFI	
In Re Application of	)	FOR: HIGH EFFICIEN	CV CARDIAC

Commissioner for Patents P. O. Box 2327 Arlington, VA 22202

Attention:

Examiner

Dear Sir:

Applicants submit herewith references of which they are aware, which they believe may be material to patentability of the invention disclosed and claimed in the above-cited application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on:

August 6, 2002
(Mailing Date)

Karen Johnson
(Typed Name)

(Signature)

August 6, 2002
(Date of Signature)

Applicants are submitting herewith copies of the references which are set forth on the attached Form PTO/SB/08A. As all relevant parts of the references are in the English language, no explanation of the references is provided herein.

This Information Disclosure Statement is submitted within three (3) months of the filing date of the above-cited application or of the date of entry into the national phase of the application or prior to the mailing date of a first Office Action thereon, whichever has occurred last, such that no fee is required.

Further, while the references provided in this Information Disclosure Statement may be material to patentability pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any reference referred to herein is prior art for this invention unless specifically designated as such.

Also, in accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(a) exists.

Respectfully submitted,

Dated: August 6, 2002

Colleen J. McKiernan

Patent Agent for Applicants Registration No. 48,570

BROWN MARTIN HALLER & McCLAIN LLP 1660 Union Street San Diego, California 92101

Telephone: (619) 238-0999 Facsimile: (619) 238-0062

Docket No.: 6627-PA0123

Approved for use through 10/31/2002. OMB 0651-0031 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

APPARE				Comple			
Substitute for form 1449A/PTO				Application Number	09/954,571		
INFORMATION DISCLOSURE				Filing Date	September 11, 20	001	
STATEMENT BY APPLICANT  (use as many sheets as necessary)			PLICANT	First Named Inventor	Kenneth CHIEN	2505	
			ssary)	Group Art Unit	1646	REC	EIVED
				Examiner Name	Unknown	AUG 1	4 2002
Sheet	1	of	4	Attorney Docket Number	6627-PA0123 7	ECH CENT	ER 1600/290

				U.S. F	ATENT DO	CUMENTS		
Cite		U.S. Patent Document		Name of Patentee or Applicant		Date of Publication of		
Examiner Initials*	No.¹	Number	Number Kind Code <sup>2</sup> (if known)			of Cited Document	Cited Document MM-DD-YYYY	
			NONE					
	-	<b>_</b>						
	-							
	†	<u> </u>						
	<del> </del>	ļ <u>.</u>						
	+-							
	<del>                                     </del>							
			ſ	OREIGI	N PATENT	DOCUMENTS		
Examiner	Cite	For	eign Patent I	Document		Name of Patentee or Applicant	Date of Publication of	
Initials*	No. 1	Office <sup>3</sup>	Number		Kind Code⁵	of Cited Document	Cited Document MM-DD-YYYY	
			NONE					

Examiner Signature	 Date Considered	
	L	L

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WPO Standard ST.3). 'For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent documents.

<sup>&</sup>lt;sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

perwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449A/PTO **Application Number** 09/954,571 September 11, 2001 Filing Date INFORMATION DISCLOSURE STATEMENT BY APPLICANT RECEIVED First Named Inventor Kenneth CHIEN 1646 Group Art Unit (use as many sheets as necessary) AUG 1 4 2002 Unknown **Examiner Name** TECH CENTER 1600/2900 2 of 4 6627-PA0123 Sheet Attorney Docket Number

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²					
	1	Arber, S., et al (1997) MLP-deficient mice exhibit a diruption of cardiac cytoarchitechtural organization, dilated cardiomyopathy, and heart failure. <i>Cell.</i> <b>88</b> :393-403.						
	2	Christensen, G. et al. (2000) High-efficiency, long-term cardiac expression of foreign genes in living mouse embryos and neonates. <i>Circulation</i> . <b>101</b> :178-84.						
	3	Coral-Vazquez, R. et al. (1999) Disruption of the sarcoglycan-sarcospan complex in vascular smooth muscle: A novel mechanism for cardiomyopathy and muscular dystrophy. <i>Cell.</i> <b>98</b> :465-74.						
	4	French, B.A. et al. (1994) Direct <i>in vivo</i> transfer into porine myocardium using replication-deficient adenoviral vectors. <i>Circulation</i> . <b>90</b> :2414-24.						
	5	Frommes, Y. et al. (1999) Gene delivery in the myocardium by intrapericardial injection. Gene Ther. <b>6</b> :683-8.						
	6	Greelish, J.P. et al. (1999) Stable restoration of the sarcoglycam complex in dystrophic muscle perfused with histamine and recombinant adeno-associated viral vector. <i>Nat. Med.</i> <b>5</b> :439-43.						
	7	Gutzman, R.J. et al. (1993) Efficient gene transfer into myocardium by direct injection of adenovirus vectors. <i>Cric. Res.</i> <b>73</b> : 1202-7.						
	8	Hajjar, R.J. et al. (1998) Modulation of ventricular function through gene transfer in vivo. Proc. Natl. Acad. Sci., USA. 95:5251-5256.						

Examiner Signature	Date Considered

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

3000

<sup>1</sup> Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent

Fkind of document by the appropriate symbols as indicated on the document under WIPO Standard ST, 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Perferond Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO **Application Number** 09/954,571 September 11, 2001 Filing Date INFORMATION DISCLOSURE RECEIVED STATEMENT BY APPLICANT First Named Inventor Kenneth CHIEN Group Art Unit 1646 AUG 4 2002 (use as many sheets as necessary) **Examiner Name** Unknown TECH CENTER 1600/2900 6627-PA0123 Sheet 3 of 4 Attorney Docket Number

9	Holt, K.M. et al. (1998) Functional rescue of the sarcoglycam complex in BIO 14.6 hamster using delta-sarcoglycan gene transfer. <i>Mol. Cell.</i> 1:841-8	
10	Johnson, L.G. (1992) Efficiency of gene transfer for restoration of normal airway epithelial function in cystic fibrosis. <i>Nat. Genet.</i> <b>2</b> :21-5.	
11	Kaplitt, M.G. et al. (1996) Long-term gene transfer in porcine myocardium after coronary infusion of an adeno-associated virus vector. <i>Ann. Thorac. Surg.</i> <b>62</b> :1669-76.	
12	Maeda, Y., et al. (1998) Efficient gene transfer into cardiac myocytes using adeno- associated virus (AAV) vectors. <i>J. Mol. Cell. Cardiol.</i> <b>30</b> :1341-8.	
13	Maurice, J., et al. (1999) Enhancement of cardiac function after adenoviral-mediated in vivo intracoronary beta-2 adrenergic receptor gene delivery. J. Clin. Invest. 104:21-9.	
14	Miyamoto, M.I., et al. (2000) Adenoviral gene transfer of SERCA2a improves left-ventricular function in aortic-banded rats in transition to heart failure. <i>Proc. Natl. Acad. Sci. USA.</i> <b>97</b> :793-98.	
15	Mohri, H. et al. (1969) Method of surface-induced deep hypothermia for open-heart surgery in infants. <i>J. Thorac. Cardiovasc. Surg.</i> <b>58</b> :262-70.	
16	Nigro, V., et al. (1997) Identification of the Syrian hamster cardiomyopathy gene. Hum. Mol. Genet. <b>6</b> :601-7.	
17	Ryoke, T., et al. (1999) Progressive cardiac dysfunction and fibrosis in the cardiomyopathic hamster and effects of growth hormone and angiotensin-converting enzyme inhibition. <i>Circulation</i> . <b>100</b> :1734-43.	
18	Sakamoto, A., et al. (1997) Both hypertrophic and dilated cardiomyopathies are caused by mutation in the same gene, delta-sarcoglycan, in hamster: An animal model of disrupted dystrophin-associated glycoprotein complex. <i>Proc. Natl. Acad. Sci. USA.</i> <b>94</b> :13873-8.	

	<del></del>	
Examiner Signature	Date Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup>Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Approved for use through 10/31/2002. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Experiment Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

- ON COM				Comple		
Substitute for form 1449A/PTO				Application Number	09/954,571	
INFORMATION DISCLOSURE				Filing Date	September 11, 2001	
	STATEMENT BY APPLICANT  (use as many sheets as necessary)			First Named Inventor	Kenneth CHIEN REC	EIVED
				Group Art Unit	1646	
		Examiner Name	Unknown	<b>1 4</b> 2002		
Sheet	4	of	4	Attorney Docket Number	6627-PA0123 TECH CEN	TER 1600/2900

1	19	Shah, A.S. et al. (2001) In vivo ventricular gene delivery of a β-adrenergic receptor kinase inhibitor to the failing heart reverses cardiac dysfunction. <i>Circulation</i> <b>103:</b> 1311.
2	20	Svensson, E.C., et al. (1999) Efficient and stable transduction of cardiomyocytes after intramyocardial infection or intracoronary perfusion with recombinant adeno-associated virus vectors. <i>Circulation</i> . <b>99</b> :201-5.
2	21	Toyofuku, E., et al. (1994) Amino acids Glu2 to Ile 18 in the cytoplasmic domain of phospholamban are essential for functional association with the Ca <sup>2+</sup> -ATPase of the sarcoplasmic reticulum. <b>269</b> :3088-94.
2	22	Xiao, X., Li, J., and Samulski, R.J. (1998) Production of high-titer recombinant adeno- associated virus vectors in the absence of helper virus. <i>J. Virol.</i> <b>72</b> :2224-32.

Examiner Signature	Date Considered	
1		

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent documents.

<sup>&</sup>lt;sup>6</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.